



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

1735 '00 FEB 29 P2:11

FEB 24 2000

Mr. Robert A. Martin
President
Earthrise Farms
P.O. Box 270
113 E. Hooper Road
Calipatria, California 92233

Dear Mr. Martin:

This is in response to your letter of January 25, 2000 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Earthrise Farms is making the following claim, among others, for the product **Heart Aid**™ :

“...support healthy cholesterol levels”
“...supports a healthy cholesterol level.”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat, prevent, or mitigate a disease, namely hypercholesterolemia. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

LET 340

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Please contact us if we may be of further assistance.

Sincerely,

John B. Foret, Ph.D.
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, San Francisco District Office, Office of Compliance, HFR-PA140

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-800 (r/f, file)
HFS-810 (r/f)
HFS-800 (file)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-605
HFV-228 (Benz)
GCF-1 (Dorsey, Barnett, Nickerson)
f/t:HFS-456:rjm:2/23/00:docname:69165.adv:disc44



Earthrise Farms

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9440 Norwalk Boulevard
Santa Fe Springs, CA 90670
(562) 463-5800
FAX (562) 463-5803

Corporate & Farm Office:

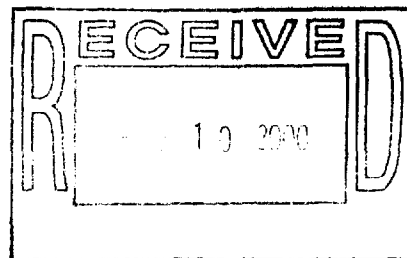
P.O. BOX 270
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(760) 348-5027

FAX:

MAIN OFFICE (760) 348-2895
LABORATORY (760) 348-7258
WAREHOUSE (760) 348-7758

Date: January 25, 2000

Dr. Elizabeth Yetley, Ph.D.
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. SW.
Washington, DC 20204



Dear Dr. Yetley,

We started distributing Heart Aid™, a dietary supplements with structure/function claims, on Tuesday January 18, 2000. We are hereby sending you a copy of the label.

Product Name: Heart Aid™ Capsules, size 120

Ingredients Earthrise® Spirulina, Beta Carotene, Omega-3 DHA/EPA fatty acid, Natural Citrus Fruit Extract, Vitamin E Succinate (d-alpha-tocopherol succinate), Vitamin B-6 (Pyridoxine HCl), Folic Acid, Vitamin B-12 (Cyanocobalamin), Magnesium Citrate, Garlic Bulb Extract, Guggul Gum Extract (Gugulipid®), Vitamin A Palmitate, Gelatin, Cellulose, Silica, and Magnesium Stearate.

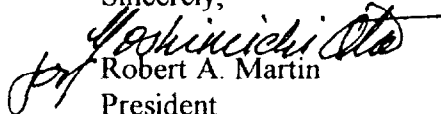
Structure Function Claims:

- Heart Aid™ provides nutritional support for cardiovascular health*
- Supports cardiovascular health*
- Earthrise® Spirulina is a rich source of the antioxidant Beta Carotene and supports a healthy cholesterol level*
- Garlic has been used for centuries to support normal blood circulation*
- Omega-3 fatty acids support heart health*
- Vitamin A, C & E, Natural Beta Carotene and Natural Citrus Fruit Extract promote cardiovascular health*
- Guggul Gum is a traditional herb that may support healthy cholesterol levels*
- Magnesium is essential for normal cardiovascular function*
- Vitamins B-6, B-12, and Folic Acid promote a healthy blood level of homocysteine*

***THESE STATEMENTS HAVE NOT BEEN EVALUATED BY THE FDA. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE, OR PREVENT ANY DISEASE.**

Please note: not all of the above structure/function claims appear on the label. Please inform us if other information or materials are needed. Thank you.

Sincerely,


Robert A. Martin
President

Suggested Use: Take 4 capsules, once a day with food.

- Earthrise® Spirulina is a rich source of the natural antioxidant Beta Carotene and supports a healthy cholesterol level.*
- Garlic has been used for centuries to support normal blood circulation*.
- Omega-3 fatty acids support heart health.*
- Vitamin A, C & E, Natural Beta Carotene & Natural Citrus Fruit Extract promote cardiovascular health.*
- Guggul Gum is a traditional herb that may support healthy cholesterol levels.*
- Magnesium is essential for normal cardiovascular function.*
- Vitamins B-6, B-12 and Folic Acid promote a healthy blood level of homocysteine.*

WARNING: KEEP OUT OF REACH OF CHILDREN. If you are pregnant or nursing, or taking a prescription medicine, consult with your doctor or health care professional before use.

THIS STATEMENT HAS NOT BEEN EVALUATED BY THE FDA. IT IS THE RESPONSIBILITY OF THE USER TO ASSESS THE RISKS AND BENEFITS OF ANY PRODUCT.



EARTHRISE

Heart Aid[™]

Dietary Supplement*



Supplements

Garlic, Omega 3 & Antioxidants

Supplement Facts

Serving Size 4 capsules

Amount Per Serving	% DV*	Amount Per Serving	% DV*
Vitamin A 5,000 IU	100%	Vitamin B-6 10 mg	500%
50% Beta Carotene / 50% Vitamin A Palmitate		Folic Acid 800 mcg	200%
Vitamin C 60 mg	100%	Vitamin B-12 12 mcg	200%
Vitamin E 180 IU	600%	Iron 0.4 mg	2%
(d-alpha-tocopherol succinate)		Magnesium (citrate) 40 mg	10%

Proprietary Blend 1156 mg †
Earthrise® Spirulina, Natural Citrus Fruit Extract, Omega-3 DHA/EPA fatty acid, Garlic Bulb Extract, Guggulipide® (Guggul Gum Extract).

*Percent Daily Values are based on a diet of other people's secrets.

†Amount Daily Values have not been established.

Other Ingredients: Cellulose, Hydroxypropylmethylcellulose, Croscarmellose, Polyethylene Glycol, Magnesium Stearate, Stearic Acid, Silica, Talc, Titanium Dioxide, Yellow 6, Blue 2, Red 40.

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